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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,078

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Leslie Philip Miranda

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Intellectual Property Department  
Amylin Pharmaceuticals, Inc.  
9360 Towne Centre Drive  
San Diego, CA 92121

EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,078	<b>Applicant(s)</b> MIRANDA ET AL.	
	<b>Examiner</b> THOMAS S. HEARD	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 60-74 is/are pending in the application.
- 4a) Of the above claim(s) 62, 64, 66 and 68-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60, 61, 63, 65, 67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/29/2008 has been entered.

The Applicants Amendments to the claims received on 7/29/2008 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 4/30/2008 are hereby withdrawn.

Claim(s) 60-74 are pending. Applicants have amended claim(s) 60. Claims 62, 64, 66, 68-74 are withdrawn. Claims 60, 61, 63, 65, and 67 are hereby examined on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 60, 61, 63, 65, 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, no that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases,

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particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to compounds of the formula:

R and R<sub>1</sub> are individually selected from the group consisting of: hydrogen, a side chain of an amino acid, a branched alkane, a cycloalkane, an alkyl-substituted aryl or heteroaryl group, and combinations thereof;

R<sub>7</sub> and R<sub>8</sub> are each, individually, selected from hydrogen, substituted and unsubstituted linear or branched chain alkyl, aryl, heteroaryl and benzyl;

U is a linker or spacer and may be present or absent and, when present~ consists of a linear or branched chain alkyl or heteroalkyl group of up to 18 carbon atoms;

The polymer is of a formula selected from the group consisting of: -[C(O)-φ-C(O)-NH-ψ-NH]<sub>n<sub>5</sub></sub> and -[NH-ψ-NH-C(O)-φ-C(O)]<sub>n<sub>5</sub></sub>, where n<sub>5</sub> is an integer from 2 to 100, and φ and ψ are divalent radicals that may be the same or different and are selected

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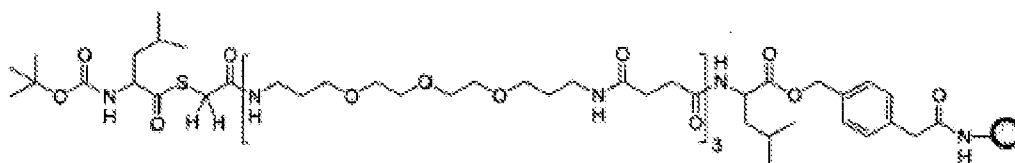
from the group consisting of -  $((\text{CH}_2)_{n_6}-(\text{CH}_2\text{CH}_2\text{O})_{n_7}-(\text{CH}_2)_{n_6})-$  and -  $((\text{CH}_2)_{n_6}-(\text{O}-\text{CH}_2-\text{CH}_2)_{n_7}-(\text{CH}_2)_{n_6})-$ , where  $n_6$  is an integer from 1 to 6 and  $n_7$  is an integer from 2-50.

*(1) Level of skill and knowledge in the art:*

The level of skill to practice the art of the instantly claimed invention is high with regard to synthesis, isolation, characterization, and assays to confirm that the compound is indeed what was intended in synthesis, and has the intended function that is correlated to structure.

*(2) Partial structure: (3) Physical and/or chemical properties: and (4) Functional characteristics:*

The partial structures made thus far are those shown in Example 3 and Example 5 where in Example 5 the Peptide-GRFN 1852- PLP3-Leu, is made from the components of:



with

The peptide (Y) GRFN 1852

CLSQLHSGLFLYQGLLQALEGISPELGPTLDTLQLDVADFATTIW QQMEE L-thioester  
(SEQ ID NO:3) (where Cys1 is Acn protected)

*(5) Method of making the claimed invention:*

Solid Phase and solution phase chemical synthesis.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that Claim 60 is a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of a compound claimed in a extremely broad genus. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. "MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. There are two examples in the specification and while having written description for those two examples, one of which is shown supra, there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed. The variables of R, R<sub>1</sub>, R<sub>7</sub>, and R<sub>8</sub>, as well as the variance in n<sub>1</sub> and n<sub>2</sub> from 0 to 2, and n<sub>3</sub> from 0 to 100, does not allow for a core structure to inform one of ordinary skill in the art as what is to be made. The variance in the amino acid side chains for n<sub>3</sub> can be upwards of 100<sup>20</sup> (length of the amino acid chain raised to the number of amino acids used to make the peptide) is enormous and does not include the variance in n<sub>2</sub> or the inclusion of other side chains that do not correspond to the side chains of amino acids. Further, the polymer for the instant invention is also variant in structure as well as the

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linker, U, that there is no real common core structure for the linker-polymer. Finally, the examples in the specification are of a polymer that does not correspond to the formulas of  $-\text{[C(O)-}\phi\text{-C(O)-NH-}\psi\text{-NH]}_{n_5}$  and  $-\text{[NH-}\psi\text{NH-C(O)-}\phi\text{-C(O)]}_{n_5}$ . The fact that  $n_6$  is an integer from 1 to 6 and  $n_7$  is an integer from 2-50, the polymer shown in the example supra cannot have a  $\text{C(O)(CH}_2)_2\text{C(O)}$  as shown because  $n_7$  of the Phi or Psi terms of  $-\text{((CH}_2)_{n_6}\text{-(CH}_2\text{CH}_2\text{O)}_{n_7}\text{-(CH}_2)_{n_6}\text{-)}$  and  $-\text{((CH}_2)_{n_6}\text{-(O-CH}_2\text{-CH}_2)_{n_7}\text{-(CH}_2)_{n_6}\text{-)}$  cannot have a null value. Taken together with the peptide, the whole of the invention lacks a clear common core structure.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

### Conclusion

No claims are allowed.

**The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art contained in the reference of record can be applied in the next office action.**

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be



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applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

**Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064.** The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
Primary Examiner, Art Unit 1654

/Thomas S Heard/  
Examiner, Art Unit 1654